DIVISION OF AGRICULTURAL
ENVIRONMENTAL SERVICES
BUREAU OF SCIENTIFIC EVALUATION
AND TECHNICAL ASSISTANCE
(850) 617-7917
(850) 617-7949 FAX

THE CONNER BUILDING, NO. 6
3125 CONNER BOULEVARD
TALLAHASSEE, FLORIDA 32399-1650

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES
COMMISSIONER ADAM H. PUTNAM

October 14, 2016

Ms. Tawanda Maignan, Team Leader
Emergency Response Team
Risk Integration, Minor Use and
Emergency Response Branch
U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, Virginia 22202

SUBJECT: Recertification Request for FireLine 17WP Bactericide/Fungicide (oxytetracycline HCL; 18.3%) EPA Reg. No. 80990-1, FireWall 50WP Bactericide/Fungicide (streptomycin sulfate; 65.8%) EPA Reg. No. 80990-3, and Mycoshield (calcium oxytetracycline; 17.7%) EPA Reg. No. 55146-97 2017 Use Season –To control HLB disease in citrus trees in Florida

Dear Ms. Maignan:

We are seeking the Agency's permission to apply the subject chemicals to meet 2017 use season requirements in Florida for providing tree health improvements in citrus trees infected with the HLB bacteria. The current exemption expires December 31, 2016. We are seeking recertification of this use by January 1, 2017. Please refer to the interim use report for 2016 (Attachment 1) and the enclosed industry letter documenting the continued need for this product (Attachment 2).

Sincerely,

Davis H. Daiker, Ph.D.
Chief, Bureau of Scientific Evaluation
and Technical Assistance

DHD/ar

Enclosures

cc: Mr. Mike Joyner
Dr. Lisa Conti
Mr. Matt Joyner
Mr. John Hoblick
Mr. Phillip Beard
Mr. Randy Dominy
Dr. Fred Fishel
Dr. Michelle Samuel-Foo
Dr. Jeanna Mastrodicasa
Mr. Anderson Rackley
Mr. Kelly Friend
Dr. Trevor Smith
Dr. Greg Hodges
Mr. Charlie Clark
Ms. Sarah Oglesby
Mr. Dale Dubberly
Mr. Neil Richmond
Ms. Patty Lucas
Ms. Teresa Rygiel
Mr. Daniel Botts
Dr. Harold Browning
Mr. Mike Aerts
Dr. Michael Rogers
Mr. Michael Stuart
Ms. Jo Marie Cook
Dr. Stephanie Slinski
Mr. Michael Sparks

October 14, 2016

Adam H. Putnam
Commissioner, Florida Department of Agriculture and Consumer Services
The Capitol
400 South Monroe Street
Tallahassee, Florida 32399-0800

Dear Commissioner Putnam:

On behalf of the Florida citrus industry, Florida Fruit and Vegetable Association, Third Party Registrations, Inc. and the Citrus Research and Development Foundation, we are once again seeking your assistance in petitioning the EPA for recertification of the Section 18 Emergency Exemptions (specific) for the use of FireWall™ 50WP Bactericide/Fungicide (streptomycin sulfate), FireLine™ 17WP Bactericide/Fungicide (oxytetracycline hydrochloride) and Mycoshield® (calcium oxytetracycline) to suppress the citrus huanglongbing (*Candidatus* Liberibacter asiaticus) (*C*Las or HLB) disease and to foster improvement in citrus tree heath following the tree's infection with the HLB organism. The information necessary for EPA to recertify these requests is enclosed. The citrus industry in Florida continues to struggle with management of HLB because there are still no other EPA-registered bactericides for prevention of infection, or for suppression of HLB, or for the improvement of health of HLB-infected trees. It remains apparent that the future of the citrus industry is still at risk and that the current HLB/tree decline/tree death situation remains an urgent, non-routine situation that if not controlled, will heavily affect the future short- and long-term economic viability of Florida's $7 billion citrus industry.

The current emergency exemptions, File symbols 16FL02 (for streptomycin) and 16FL03 (for oxytetracycline), will expire on December 31, 2016. As both the registration status of the above-mentioned bactericides and the current emergency condition surrounding this situation remain unchanged at this time, we are requesting a recertification of these exemptions to assist with the continued improvement of citrus tree health.

P.O. Box 948153, Maitland, FL 32794-8153 • 800 Trafalgar Court, Suite 200, Maitland, FL 32751
321.214.5200 • fax 321.214.0210 • www.ffva.com

Since the issuance of the Crisis Declaration on March 4, 2016, Florida growers have used all three products as shown in the table below (March, 2016 – September, 2016)*:

Product	Pounds of Formulated Product	Pounds of Active Ingredient
FireWall™ 50 WP	231,761	115,881 (streptomycin)
FireLine™ 17 WP	612,657	104,152 (oxytetracycline)
Mycoshield ®	634,000	107,865 (oxytetracycline)

*estimated based on product sales and distribution system inventories.

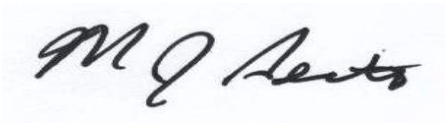
Citrus producers made an overall average of approximately two antimicrobial applications to approximately 84 percent of their citrus acreage. The number of applications ranged from zero to 11, with the majority of the acreage receiving between two and six antimicrobial sprays. Albeit somewhat subjective, the impact on HLB and tree quality is the only post-application response information available at the present time. Most growers utilizing these antimicrobials are reporting an indication of improved tree health, with greater impact being observed on younger trees/groves.

Since this disease's appearance in 2005, citrus production has been compromised with the loss of millions of trees, and HLB has subsequently been detected in every county with commercial citrus. Without access once again to these antimicrobial products, trees infected with HLB will continue to decline and eventually die, even when incorporating all other HLB management options available to the industry at this time.

The availability of multiple antimicrobial products that enable strategies to be developed for improvement of fruit production and fruit retention must remain in place for the industry to counter the impacts of this disease. Without access to these antimicrobials, within five to eight years of becoming infected, diseased trees will no longer be economically productive. Therefore the continued availability of FireWall™ 50WP, FireLine™ 17WP and Mycoshield® will give producers options to utilize in their struggle to combat this disease and the worsening/intensifying devastation that HLB is causing.

Thank you in advance for your attention to this matter. If you, or anyone else within the Department, have any questions regarding this request, please do not hesitate to call.

Sincerely,



Michael J. Aerts
Director; Production and Supply Chain Management

cc: Davis Daiker; FDACS (w/o attachments)
Mike Joyner; FDACS (w/o attachments)
Lisa Conti; FDACS (w/o attachments)
Taw Richardson; AgroSource, Inc.
Bill Bewlay; Nufarm Americas, Inc.
Harold Browning; Citrus Research and Development Foundation
Randy Dominy; EPA Region 4

Recertification Request

Tree Health Section 18 for the use of Antibiotics to Suppress Huanglongbing and Improve Tree Health of Citrus in Florida (EPA File Symbol 16FL02 and 16FL03)
Expiration Date: December 31, 2016

Supplemental Information to Petition Dated: December 2, 2015

The specific products requested remain the same as with the initial petition:

FireWall™ 50 WP, EPA Reg. No. 80990-3/16FL02, Streptomycin Sulfate
65.8 % Streptomycin Sulfate, equivalent to 50% Streptomycin

FireLine™ 17 WP, EPA Reg. No. 80990-1/16FL03, Oxytetracycline Hydrochloride
18.3 % Oxytetracycline Hydrochloride, equivalent to 17 % Oxytetracycline

Mycoshield®, EPA Reg. No. 055146-97/16FL03, Calcium Oxytetracycline
17.7 % Calcium Oxytetracycline, equivalent to 17 % Oxytetracycline
(Active Ingredient nomenclature change, same EPA Reg. No.)

The registrants have indicated their support for the registration of these products via section 3 label PRIA requests (AgroSource, Inc., FireWall 50 WP in October, 2015 and FireLine 17 WP in November, 2015; Nufarm, Mycoshield in September, 2016). They have indicated support for this renewal as shown in the attached authorization letters (Appendix 1). The labels remain unchanged from those approved by the agency in their August 15th letter (Attached, Appendix 2).

Alternatives Research:

As strongly suggested in the authorization letter, the industry continues to seek alternative treatments to the use of antibiotics. The research efforts continue under the guidance of the Citrus Research and Development Foundation. While the most promising of the long term management options appear to be dependent on new technologies, i.e., transgenic plants, gene activation technologies and novel uses of RNAi and other genomic based tactics; there is one potential tool in the development pipeline that may substitute for the use of antibiotics.

Potential new pesticides, including conventional pesticides, true biopesticides, and minimum-risk pesticides are being evaluated in laboratory, greenhouse and field studies. A new zinc-based treatment has been developed and is being evaluated in several field trials to improve the formulation against HLB, to develop field application recommendations, and to examine the economics of grower use. Studies are also taking place to support a Section 3 application. This Section 3 application package will not be complete for several years, this product may have a more extended registration process compared with biopesticides and these materials are still unproven as a HLB therapy, but if effective it would be a substitute for antibiotics. Other research programs are attempting to identify viable alternatives to antibiotics. Researchers at

the University of Florida have been funded to test antimicrobial materials that have been found to specifically target the HLB causal bacterium in both the greenhouse and field. The results of these trials are promising, but these are new active ingredients for use in agriculture and are not near-term therapies for HLB.

All of these options are multiple years away from registration and use in the Florida industry.

Commercial Use During the Crisis/Section 18 Period:

With the issuance of the Crisis Declaration by Florida department of Agriculture and Consumer Services Commissioner Adam Putnam, in March 2016, Florida growers have used all three products as shown in the table below (March, 2016 – September, 2016)*:

Product	Pounds of Formulated Product	Pounds of Antibiotic
FireWall™ 50 WP	231,761	115,881 (Streptomycin)
FireLine™ 17 WP	612,657	104,152 (Oxytetracycline)
Mycoshield ®	634,000	107,865 (Oxytetracycline)

*estimated based on product sales and distribution system inventories.

Grower Survey, Florida Citrus Expo, August 2016:

In an effort to gain a better understanding of what growers are doing with approved bactericides this season and to share this information with growers while we all wait for evidence of impact to appear later in the season, CRDF partnered with Agnet Media to conduct a short survey which would characterize the patterns of use of the bactericides. This survey included bactericides already applied this season, as well as season-long plans.

One hundred growers responded to eight questions that captured grove situations and use of bactericides. The acreage managed by these growers is 202,379 acres oranges, 29,525 acres grapefruit and 8,401 specialty fruit; this represents nearly fifty percent of Florida's citrus acreage. A large percentage of the growers who responded to the survey manage less than 500 acres of citrus, and these growers represented 3% of the reported acreage in this survey. A much smaller percentage of growers who responded each manage more than 10,000 acres, and represent 53% of the total reported acreage. The 240,305 acres represented in these survey results were spread across Florida's major production regions. All but seven of the survey respondents applied at least one treatment with bactericides since March. Of those that have not applied bactericides, only one does not plan to apply them. An average of approximately two applications were made at the time of this survey.

Respondents reported that they intend to apply between zero and eleven applications this season, the majority of respondents planned for two to six (figure 1). An average of approximately two applications were made at the time of this survey. When asked what percent of their acreage they intend to treat during this season, the response was a weighted average of 84%, or approximately 201,724 acres. Two thirds indicated that they would treat all of their acreage with these bactericides.

Two-thirds of those who completed the survey indicated that they were rotating the two active ingredients, streptomycin and oxytetracycline, while some respondents reported using one or the other active ingredient exclusively. The growers rotating materials represent 219,889 of the 240,305 acres in this survey.

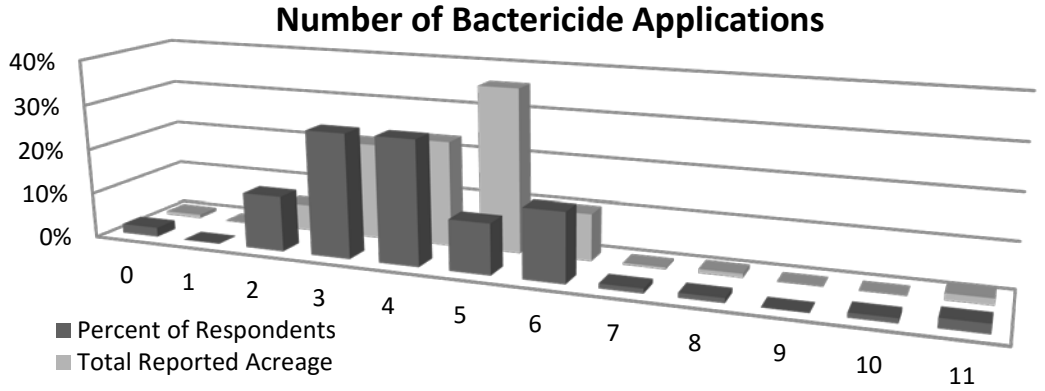


Figure 1

Impact of Use of the Products:

The impact on HLB and tree quality is only anecdotal at the present time, most growers are reporting indications of increased tree health with greater impact on younger groves. The collection of yield data will take place with harvest from treated groves during the 2016/2017 harvest season. The current efficacy data from treatments during the 2015/2016 will not be completed form the Registrant initiated trials until fall harvest takes place. Limited interim data has been supplied by AgriSource, Inc. and is included in Appendix 4. Nufarm is in the process of collecting and analyzing the data from their most recent research trial period. Because of the limited data available under commercial field use, the Citrus Research and Development Foundation has initiated a process to provide growers with the tools to allow a comparative assessment on their farms as they use these products this season. A guidance document was provided to the industry in early April that provided growers with a standard set of data to be collected. Due to the seasonality of the data collections and the need to have end of season harvest information this information will not be available until sometime next year. For a group of voluntary participants CRDF is also providing more comprehensive support to support collection of information across multiple defined use scenarios and cropping systems. This project is described in more detail below.

No adverse impacts have been reported at this time.

CRDF GROWER BACTERICIDE TRIALS

The strategies for the best use of FireWall™ 50WP, FireLine™ 17WP and Mycoshield® on citrus against HLB have not yet been developed. The registrants have been evaluating these materials for efficacy, but trials evaluating the best-use patterns have only recently been implemented. In order to provide growers with information on how effective their treatments were at improving tree health, a series of field trials have been established throughout the citrus growing regions of Florida on the major citrus varieties. These field trials are basic trials of side-by-side treated and untreated blocks or rows. CRDF field staff is evaluating these trials periodically for bacterial titer, disease severity, changes in fruit drop and yield. These evaluations will continue for the duration of the Section 18 use of FireWall™ 50WP, FireLine™ 17WP and Mycoshield®.

More than seventy field trials were set-up in the three months following the crisis declaration on March 5, 2016. Approximately forty-one trials are in Valencia orange blocks, sixteen in Hamlin orange, eleven in grapefruit and six in other varieties. These trials will be analyzed as the data is collected in order to provide growers with information on the effect of their treatments, to help develop best-use patterns, and to support the Section 18 renewal.

Status of the Disease Economic Loss in Florida Citrus:

The startling downward trend in yield and quality continues as documented in the year by year losses by the National Agricultural Statistics Service, the 2015- 2016 crop production numbers detail an additional double digit percentage drop from the previous season.

Crop Production by Fruit Type 1996-1997 through 2014-2015

Crop Year	Oranges	Grapefruit	Other Citrus	Total
2011-2012	146,600	18,850	5,440	170,890
2012-2013	133,600	18,350	4,280	156,230
2013-2014	115,000	16,500	4,400	135,900
2014-2015	96,700	12,950	2,980	112,630
2015-2016	81,500	10,850	2,060	94,410

Season to Season		Percentage Decline
2010-2011 to 2011-2012		9.0%
2012-2013 to 2013-2014		11.0%
2013-2014 to 2014-2015		17.0%
2013-2014 to 2015-2016		16.0%
Net loss (4 years)	**=**	**39.6%**

Progress Toward Registration:

As acknowledged previously, both registrants have submitted full registration petitions to the Agency for these uses for Crop Group 10, Citrus. The most recent submission by Nufarm was made in September and includes the residue package to support establishment of tolerances for oxytetracycline across all citrus varieties. The list of studies submitted with that petition as well as the residue study is attached in Appendix 5.

Resistance Monitoring:

Both companies have initiated studies to determine the impact on microbiological communities for their individual products. Those studies are on-going and the results will be submitted with the final report scheduled for mid-2017. Protocols for those studies are included in the Appendix 4 and 5. TPR, Inc., CRDF and FDACS are developing a protocol to provide similar information when all products are used in a coordinated program. That protocol will be provided to the Agency one completed to allow initiation of the study with the first applications during the 2017 production cycle. We anticipate coordination with the Agency as that protocol is refined and finalized.

Total Amounts Requested for Use During 2017:

Based on the survey results and projections of use during 2016, we would modify the amounts requested of each product as shown in Table 2. The total acres to be treated would be reduced to 85 % (330,254 acres) of the acreage requested for 2016.

Table 2: Amounts of Material Requested for Use During 2017 Citrus Production Season.			
Maximum Amount –Active ingredient	**341,813 lbs. Streptomycin**	**673,718 lbs. Oxytetracycline Annual Total Across Both Formulated Products**	
Maximum Amount – Formulated Product	**683,626 lb. Firewall™ 50 WP** 330,254 acres X 2.07 lb. **Firewall™ 50 WP**/acre/year = 683,626 lb. **Firewall™ 50 WP** 683,626 lb. X 50 % = 341,813 lb. Streptomycin 683,626 lb. X 65.8 % = 529,201 lb. Streptomycin Sulfate	**1,486,143 lb. FireLine™ 17 WP** 330,254 acres X 4.5 lb. **Fireline™ 17** WP/acre/year = 1,486,143 lb. **FireLine™ 17 WP** 1,486,143 lb. X 17 % = 252,644 lb. Oxytetracycline 1,486,143 lb. X 18.3 % = 271,964 lb. Oxytetracycline Hydrochloride	**3,963,048 lb. Mycoshield®** 330,254acres X 12.0 lb. **Mycoshield®** acre/year = 3,963,048 lb. **Mycoshield®** 3,963,048 lb. X 17 % = 673,718 lb. Oxytetracycline 3,963,048 *lb.* X 17.7 % = 701,460 lb. Calcium Oxytetracycline